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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,514	04/30/2001	K. Roger Aoki	D2929CON	3428

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,514	AOKI ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- Th MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,17-26,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,17-26,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed October 16, 2003. Claims 1, 17 and 26 have been amended.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejection Withdrawn

3. In view of Applicant's amendment and Response, the rejection of claims 1-9 and 17-26 under 35 U.S.C. 112, second paragraph, page 2, paragraph 4 has been withdrawn.

Rejections Maintained

4. The rejection of claims 1, 6, 17, 22 and 26-27 under 35 U.S.C. 103(a) as unpatentable over Ludlow et al in view of Schantz et al is maintained for the reasons set forth on, pages 3-4, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Ludlow et al teach the use of a composition comprising Botulinum toxin type F to treat Torticollis, (a neuromuscular disorder or condition).

Ludlow et al do not teach using a composition comprising at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G to treat patients suffering from torticollis.

Schantz et al teach that Botulinum toxin A can provide profound symptomatic relief from humans suffering from a wide variety of disorders characterized by involuntary movements of muscle groups (including torticollis) (page 83, 2nd column and page 84, Table 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use a combination of Botulinum toxin type A as taught by Schantz et al and Botulinum toxin type F as taught by Ludlow et al in the

method of treating patients against torticollis because Ludlow et al has demonstrated that Botulinum toxin F can be used to treat patients suffering from neuromuscular disorders or conditions and Schantz et has taught that Botulinum toxin A can provide profound symptomatic relief from patients suffering from a wide variety of neuromuscular disorders or conditions.

In re Nilssen (7 USPQ 2d 1500) states:

> ...The board attributes to the "hypothetical person" knowledge of all prior art in the field of the inventor's endeavor and of the prior art solutions for a common problem even if outside that field.
>
> We reject that recommendation as contrary to our precedent, which holds that for the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references.

Therefore, "it is *prima facie* obvious to combine two compositions each of which is taught in the art to be used for the very same purpose: idea of combining them flows logically from their having been individually taught in the prior art".

Applicant urges that the Office action has failed to establish a *prima facie* case of obviousness. Applicant urges that the Office action fails to provide suggestion or motivation to combine the two prior art references. Applicant urges even if the reference could be combined the combination fails to disclose, teach or even suggest all of the limitations recited in the present claims. Applicant urges that the rejection is based on the Examiner's opinion that it would have been obvious to one of skill in the art at the time the invention was made to combine two compositions each containing a single neurotoxin based on the idea that combining them flows logically from [single neurotoxins] having been individually taught in the prior art.

Applicant's arguments filed October 16, 2003 have been fully considered but they are not persuasive. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that

obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

5. The rejection of claims 1, 6, 17, 22 and 26-27 under 35 U.S.C. 103(a) as unpatentable over Ludlow et al in view of Tsui et al is maintained for the reasons set forth on, pages 5-6, paragraph 6 of the previous Office Action.

The rejection was on the grounds that Ludlow et al teach the use of a composition comprising Botulinum toxin type F in to treat torticollis.

Ludlow et al do not teach using a composition comprising at least two neurotoxins selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

Tsui et al teach a composition comprising botulinum toxin A and normal saline used to treat spasmodic torticollis, (neuromuscular disorder or condition) (page 245, 2nd column).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use a composition comprising a combination of Botulinum toxin type A as taught by Tsui et al and Botulinum toxin type F as taught by Ludlow et al in the method of treating patients against torticollis because Ludlow et al has demonstrated that Botulinum toxin F can be used to treat patients suffering from torticollis and Tsui et al has demonstrated the efficacy and safety in the treatment of spasmodic torticollis using compositions comprising Botulinum toxin A (page 246, 2nd column).

In re Nilssen (7 USPQ 2d 1500) states:

> ...The board attributes to the "hypothetical person" knowledge of all prior art in the field of the inventor's endeavor and of the prior art solutions for a common problem even if outside that field.
>
> We reject that recommendation as contrary to our precedent which holds that for the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references.

Therefore, "it is *prima facie* obvious to combine two compositions each of which is taught in the art to be used for the very same purpose: idea of combining them flows logically from their having been individually taught in the prior art".

Applicant urges that the Office action has failed to establish a *prima facie* case of obviousness. Applicant urges that the Office action fails to provide suggestion or motivation to combine the two prior art references. Applicant urges even if the reference could be combined the combination fails to disclose, teach or even suggest all of the limitations recited in the present claims. Applicant urges that the rejection is based on the Examiner's opinion that it would have been obvious to one of skill in the art at the time the invention was made to combine two compositions each containing a single neurotoxin based on the idea that combining them flows logically from [single neurotoxins] having been individually taught in the prior art.

Applicant's arguments filed October 16, 2003 have been fully considered but they are not persuasive. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

6. The rejection of claims 1-9 and 17-29 under 35 U.S.C. 103(a) as unpatentable over Ludlow et al and Schantz et al and further in view of Sugiyama is maintained for the reasons set forth on, pages 6-7, paragraph 7 of the previous Office Action.

The rejection was on the grounds that The combination of Ludlow et al and Schantz et al as set forth *supra* differs by not teaching the combination of A and B or A and E.

Sugiyama teaches that are seven (A-G) known serotypes of botulinum toxin that have been isolated and characterized. Sugiyama teaches antigenically different neurotoxins have a common and unique pharmacological action (page 427, 2nd column).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute any of the B,C,D,E or G for the "F" neurotoxin in the combination of Ludlow et al and Schantz et al as combined *supra* because Sugiyama teaches that these antigenically different neurotoxins have a common and unique pharmacological action and the substitution of the one for the other would be readily expected to work given that two of the individual neurotoxins have been individually shown to be effective for the treatment of torticollis.

Applicant urges that the Office action has failed to establish a *prima facie* case of obviousness. Applicant urges that the Office action fails to provide suggestion or motivation to combine the two prior art references. Applicant urges even if the reference could be combined the combination fails to disclose, teach or even suggest all of the limitations recited in the present claims. Applicant urges that the rejection is based on the Examiner's opinion that it would have been obvious to one of skill in the art at the time the invention was made to combine two compositions each containing a single neurotoxin based on the idea that combining them flows logically from [single neurotoxins] having been individually taught in the prior art of the substitution of one

[neurotoxin] for the other would be readily expected to work given that two of individual neurotoxins have been shown to be effective for the treatment of torticollis.

Applicant's arguments filed October 16, 2003 have been fully considered but they are not persuasive. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

7. The rejection of claims 1, 6, 17, 22 and 26-27 under 35 U.S.C. 103(a) as unpatentable over Ludlow et al and Schantz et al and further in view of Sugiyama is maintained for the reasons set forth on, pages 7-8, paragraph 8 of the previous Office Action.

The rejection was on the grounds that the combination of Ludlow et al and Schantz et al as set forth *supra* differs by not teaching the combination of more than 2 or all botulinum neurotoxins.

Sugiyama teaches that are seven (A-G) known serotypes of botulinum toxin that have been isolated and characterized. Sugiyama teaches antigenically different neurotoxins have a common and unique pharmacological action (page 427, 2nd column).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add any one of or all of the B,C,D,E or G botulinum toxins to the "A and F" neurotoxin combination of Ludlow et al and Schantz et al as

combined *supra* because Sugiyama teaches that these antigenically different neurotoxins have a common and unique pharmacological action and the addition of any or all of these neurotoxins would be readily expected to work given that two of the individual neurotoxins have been individually shown to be effective for the treatment of torticollis.

Applicant urges that the Office action has failed to establish a *prima facie* case of obviousness. Applicant urges that the Office action to fails to provide suggestion or motivation to combine the two prior art references. Applicant urges even if the reference could be combined the combination fails to disclose, teach or even suggest all of the limitations recited in the present claims. Applicant urges that the rejection is based on the Examiner's opinion that it would have been obvious to one of skill in the art at the time the invention was made to combine two compositions each containing a single neurotoxin based on the idea that combining them flows logically from [single neurotoxins] having been individually taught in the prior art.

Applicant's arguments filed October 16, 2003 have been fully considered but they are not persuasive. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
January 5, 2004

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